

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Matter of:

ECUMED HEALTH GROUP
a corporation,

and

AMADOR REYES,
JUAN C. CARRAI,
RICHARD W. STONE, M.D. and
ERLINDA B. ENRIQUEZ, M.D.
Individuals.

FDA Docket: 2004H-0322

**ERLINDA E. ENRIQUEZ, RECOMMENDED FINDINGS WITH REGARD TO PENALTY
AND REQUEST TO CROSS EXAMINE WITNESSES**

Recommended Findings Relevant to Penalty

In light of this honorable hearing officer's granting of partial summary judgement in favor of the Complainant, Erlinda Enriquez would propose the following findings with regard to penalty:

1. Dr. Enriquez has denied actual knowledge of the unlicensed status in her response to the Complaint for Civil Money Penalties and although there has been a ruling that finds she must have at least had constructive knowledge, she has denied ever receiving the actual correspondences from the FDA.
2. No evidence has been offered by any parties to counter such denial or confirm that any such correspondences were forwarded to Dr. Enriquez. undersigned believes that this can be proven by cross examination of the Co-Respondents Carrai and Reyes.
3. That although Erlinda Enriquez was found to have constructive knowledge of the unlicensed status, for the purpose of penalty it should be considered that the aiding and abetting of the unlicensed activity was unintentional and that Dr. Enriquez was not made aware of the inspections, correspondences and interactions between Ecumed, its principals and the FDA.
4. That the penalty sought by the FDA is excessive considering this lack of evidence of any wrongful intention on the part of Erlinda Enriquez, M.D.

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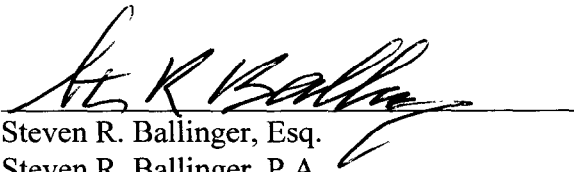
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5. That As for the penalty, Dr. Enriquez is married and her husband was in no way involved in, or participated in her dealings with EHG; his income is therefore irrelevant to this matter.
6. That the penalty sought by the FDA exceeds the gross income of Dr. Enriquez for the preceding three years and is therefore excessive (see attached Proffer as To Penalty) and records previously produced to Complainant.

Request to Cross Examine Witnesses Juan C. Carrai and Amador Reyes

1. Dr. Enriquez has denied receipt of the correspondences from the FDA and there has been no evidence of contact between Dr. Enriquez and the FDA except a broad Statement by Juan C. Carrai that the "doctors were the contacts for all communications with regulatory agencies." (Declaration of Carrai, p. 2, Number 7).
2. Amador Reyes also alleges the any regulatory responsibilities were that of the physicians without any indication of them having actually been made aware of them.
3. Erlinda Enriquez, M.D. believes that cross examination of Juan C. Carrai and of Amador Reyes will confirm that she was not involved in the regulatory matters as they allege.
4. Cross examination of these witnesses should not exceed several hours.

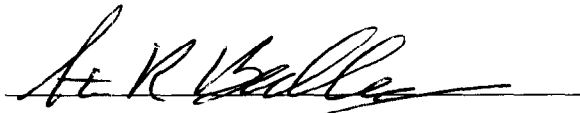
Respectfully submitted this 29 day of July, 2005,


Steven R. Ballinger, Esq.
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Certificate of Service

I hereby certify that original was sent to the Division of Dockets Managements, Food and Drug

Administration, 5630 Fishers Lane, Room 1061 (HA-305), Rockville, MD 20852 via FedEx overnight with copies by facsimile and regular mail to Michael N. Varrone, Department of Health and Human Services, Office of the General Counsel, Food and Drug Division, 5600 Fishers Lane, Room 6-39 (GCF-1), Rockville MD 20857, Franklin G. Cosmen, Jr., Fowler White, et al. 1395 Brickell Avenue, Miami, Florida 33131-3302, Mario Delgado, Esq. 2000 Ponce de Leon Blvd, Suite 102, Coral Gables, Florida 33134, Michael S. Kaufman, 11900 Biscayne Blvd. Ste. 511, Miami, Florida 33181 on July 29, 2005.

A handwritten signature in black ink, appearing to read "S. R. Ballinger", written over a horizontal line.

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**ERLINDA E. ENRIQUEZ, M.D.'S SUPPORTING DOCUMENTATION TO PROPOSED
FINDINGS OF FACT RELATIVE TO PENALTY**

Respondent, ERLINDA B. ENRIQUEZ, M.D., swears and affirms the following facts:

1. I am not, nor have I ever been a director or owner of Ecumed Health Group (EHG) or the radiological facilities that are the subject matter of this action.
2. I was never offered, nor was I ever paid any additional remuneration for any additional services or offices at EHG, other than to interpret X-ray.
3. I never received any correspondences from the Food and Drug Administration or the American College of Radiology in my office; I was never provided with any correspondences from those entities by Ecumed and was completely unaware of any issues with regard to EHG's licensure.
4. I did not spend any time in the EHG center and was not aware of any mail having been sent there under my name.
5. I was not aware of the federal laws applicable to the licensure of Radiological centers, nor was I aware that ACR accreditation was tied to the licensing of the facility; any documents I did sign were at the behest of the principals of EHG and I did not intend, nor was I given any remuneration too become the center's "lead interpreting physician."
6. As for the penalty, I am married and my husband was in no way involved in, or participated